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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,111	11/14/2003	Charles D. Claude	50623.337	2722

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EXAMINER	
MULLIS, JEFFREY C	

ART UNIT	PAPER NUMBER
1711	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,111	CLAUDE, CHARLES D.	
	Examiner	Art Unit	
	Jeffrey C. Mullis	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 31-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-25, 5-24*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election without traverse of Group II and the species wherein the R1 in the block copolymer is COO-hydroxyethyl and R2 is H in the block copolymer species and antiproliferatives as the species of agent and stents as the medical device in the reply filed on 5-25-05 is acknowledged.

Applicant's' discussion in paragraphs 22 and 24 (with reference to the published application) that the cited references disclose production of the macromer having the structure in paragraph 22 is incorrect as the examiner sees nothing in the cited references re polymerization of vinylidene fluoride and HFP in the presence of 1, 2 diiodo tetrafluoroethylene to produce the macromer shown in paragraph 22. Explanation is required and correction of the specification needed if the examiner is correct. In any case the examiner accepts applicant's explanation that the macromer may be produced by "standard radical polymerization". Although the polymerization appears to involve perfect alternating copolymerization of HFP and vinylidene difluoride with complete head to tail polymerization of the two monomers and would appear to be unusual, the examiner is in no possession of information indicating that those skilled in the art would doubt applicants disclosure that the macromer produced in paragraph 22 was produced by the disclosed polymerization process and thus there is no question of lack of enablement.

Claims 16-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants specification discloses that applicants non fluorinated block may have fluorinated substituents and it is therefore unclear what applicants intend by the term non-fluorinated".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamabe et al. (US 4,412,054).

Yamabe discloses the production of a nonthronmogenic tube coated with block copolymer containing a fluorinated and nonfluorinated block and as the tube is nonthrombogenic could said to be implantable. See the Abstract and Example 1. Note that the product of patentees is disclosed to be useful as artificial organs etc at column 1, lines 5-10.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Grimminger et al. (US 5,219,662).

Grimminger discloses a composition for treating vascular grafts or artificial heart parts with a block copolymer having a fluorinated and nonfluorinated block. Note the abstract and column 3, lines 5-20. Note column 4, lines 10-26 for coating of tubes using the block copolymers.

Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimminger et al., cited above in view of Sirhan et al. (PGPUB 2002/0082679) and Chudzik (US 6,344,035).

The primary reference does not disclose coating a stent but discloses a wide range of implants including those useful in heart treatment at column 3, lines 30-40. Also the primary reference does not disclose the use of a bioactive agent/drug.

The secondary reference Sirhan at paragraphs 22 and 23 disclose an "expandable structure" such as a sent which may be comprised of polymers and a "therapeutic agent" associated with said structure (paragraph 24), such agents including everolimus for reducing inflammation and immunosuppressant at paragraph 89.

Chudzik at column 1, lines 20-33 discloses complications from use of a foreign body and as a solution to the problem discloses a coating agent which is a polymer and a bioactive agent at column 5, lines 35-51 (note also that the implants include stents).

It would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to use the stent of the secondary references as the implant of the primary reference motivated to extend the usefulness of the process of the primary reference and motivated by the need for a specific implant to practice the process of the primary reference, absent any showing of surprising or unexpected results.

With re to addition of bioactive agents to the coating of the primary reference, it would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to add drugs to the coating of the primary reference, since the secondary references disclose that his may be done to treat problems associated with implants

and motivated to reduce the problems associated with implantation, absent any showing of surprising or unexpected results.

Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over . Yamabe, in view of Sirhan et al. (PGPUB 2002/0082679) and Chudzik (US 6,344,035), all cited above.

The primary reference does not disclose coating a stent but discloses that the products produced are useful as medical appliances for contact with blood at column 1, lines 5-12. Also the primary reference does not disclose the use of a bioactive agent/drug.

It would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to use the stent of the secondary references as the implant of the primary reference motivated to extend the usefulness of the process of the primary reference and motivated by the need for a specific medical appliance to practice the process of the primary reference, absent any showing of surprising or unexpected results.

With re to addition of bioactive agents to the coating of the primary reference, it would have been obvious to a practitioner having an ordinary skill in the art at the time of the invention to add drugs to the coating of the primary reference, since the secondary references disclose that his may be done to treat problems associated with implants and motivated to reduce the problems associated with implantation, absent any showing of surprising or unexpected results.

Tatemoto et al. (US 4,158,678) appears to inherently disclose applicants block copolymers having the fluorinated block as in claim 17 in some examples (example 5 for instance) but does not suggest its use as a coating for a medical device or any article which would reasonably appear to read thereon.

Any inquiry concerning this communication should be directed to Jeffrey C. Mullis at telephone number 571 272 1075.

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7-16-05

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